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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/417,522	10/13/99	MEHLS	M 9535-027-999

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EXAMINER	
MORAN, M	
ART UNIT	PAPER NUMBER
1631	4

DATE MAILED: 07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/417,522	NEHLS ET AL.	
	Examiner	Art Unit	
	Morjorie Moran	1631	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other *detailed action*

All rejections and objections not repeated below are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 8 and 9 are objected to because of the following informalities: the phrase "said templates are" should be --said template is-- in each claim. Appropriate correction is required.

35 U.S.C. 101/112 Utility Rejections

Claims 3 and 5-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Applicant's arguments filed 4/24/01 have been fully considered but they are not persuasive.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid. As previously set forth in the office action of 10/24/00, the specification states (on pages 2-3) that the nucleic acid compounds may be useful in methods to analyze biopolymer sequences, as hybridization probes, and for screening libraries. Also as previously set forth, these are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed.

The specification also discloses on page 8 that the claimed nucleic acid sequences may be used as markers to detect diseases, biological events, cell types, and tissues. However, the specification fails to disclose a nexus between any, or all, of the claimed nucleic acid sequences and any particular disease, biological event, or cell or tissue type. Applicant argues in the response filed 4/24/01, and the specification discloses on page 12, that the claimed nucleic acid sequences may be used for diagnostic gene expression and analysis, in cross species hybridization analysis, for antisense inhibition, for gene targeting, therapy and delivery, for identifying exon splice junctions, and in chromosome mapping. Again, the instant specification fails to provide a nexus between specific sequences, as identified by SEQ ID NO's and a particular gene, disease, splice junction, of chromosome. Nor does applicant provide such information in any other format (e.g. a Table or Figure, a declaration, or by pointing to the teachings of the prior art for a "known" connection between a sequence and a particular disease, etc.) As almost any nucleic acid sequence may be used in hybridization studies and in antisense inhibition assays, these are considered uses which are applicable to any nucleic acid sequence, and thus are not considered specific, substantial, and credible utilities for the nucleic acids claimed. Some uses, such as diagnostic gene expression assays, genomic and chromosome mapping, and identification of (or use as a marker for) diseases, biological events, tissues, etc. are utilities which apply to a subset of all nucleic acid sequences. For example, identification of exon splice sites is a utility which would presumably apply only for nucleic acid sequences derived from eukaryotic organisms. There is no evidence that this is necessarily the case, however, and the uses set forth above are still those which apply to a wide variety of nucleic acid sequences. As no diseases, tissues, etc. are disclosed for which the claimed sequences are specific, the utilities set forth in the specification and the arguments are not specific, substantial, and credible utilities. It is noted that a method of making a compound or composition which does not have utility also does not have utility.

Applicant also argues in the response filed 4/24/01 that the utility of the claimed nucleic acid sequences is to "expand" the utility of current genomic data and to identify

poorly expressed genes in raw genomic sequences. While these uses are certainly interesting and "useful" from a research point of view, they do not constitute a specific, substantial, and credible utility under 35 USC 101. While identification of a gene with a well-established utility may confer utility on a sequence which can identify said gene, no genes with a well-established utility are specifically disclosed by the instant specification which can be or have been identified by the claimed nucleic acid sequences. The specification, in fact, fails to disclose a relationship between any known gene and a claimed nucleotide sequence. Applicant is reminded that a "use" to do further research (e.g. to identify an unknown gene) is not considered a specific, substantial, and credible utility. As set forth above, a method of making a compound without utility does not itself have utility. The same is true for a method of use of a compound without utility. While a method of use may confer utility on a compound (e.g. to detection of a specific disease confers utility on the compound so used), a use to make or detect a compound which itself does not have utility does not confer utility on either the compound made or the method of making or the method of use.

For the reasons set forth above, applicant's arguments are not convincing, the rejections of claim 3 is maintained, and claims 5-13 are rejected.

Claims 3 and 5-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. While one skilled in the art would know how to make the compounds recited in claims 5-9, one would not know how to use the compounds thus made, therefore claims 3 and 5-13 are not enabled.

Claim Rejections - 35 USC ' 112

Claims 3 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 4/24/01 have been fully considered but they are not persuasive. The arguments are addressed below.

The specification discloses SEQ ID NO's 9-18 which correspond to cDNA/genomic DNA. Applicant argues that the claimed sequences are identified by structure/formula (i.e. sequence) and/or by functional property (i.e. ability to hybridize to certain sequences). The specific sequences corresponding to SEQ ID NO's 9-18 meet the written description provisions of 35 USC 112, first paragraph. However, claims 3 and 10-13 recite open claim language (e.g. comprising) and are therefore also directed to encompass gene sequences, sequences that hybridize to SEQ ID NO's 9-18, corresponding sequences from other species, derivatives, allelic variants, splice variants, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the specific sequences corresponding to SEQ ID NO's 9-18, the skilled artisan cannot envision the detailed chemical structure of the

encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further

> information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only polynucleotide sequences consisting of SEQ ID NO's 9-18, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) While claim 13 does not itself recite a an isolated polynucleotide sequences "comprising" ...., it depends from claim 3, 10, or 11, all of which do recite such sequences. For the reasons set forth above, applicant's arguments are not convincing, the rejection of claim 3 is maintained and claims 10-13 are rejected.

Claim Rejections - 35 USC § 102

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by each of HOOF *et al.* (I), CHU *et al.* (J), and SAHA *et al.* (K)

HOOF, CHU, and SAHA independently teach oligonucleotides each comprising a contiguous stretch of 29 bases with 100% identity to residues 30-59 of SEQ ID NO. 16 (see alignments). Residue 60 of instant SEQ ID NO: 16 is designated "n", which may be any nucleic acid, and is therefore interpreted to be a "C" (as in the sequences of HOOF, CHU, and SAHA). Residues 62-63 of instant SEQ ID NO: 16 also match the sequences of HOOF, CHU, and SAHA, therefore HOOF, CHU, and SAHA each teach

an oligonucleotide comprising a contiguous stretch of at least about 30 nucleotides of SEQ ID NO: 16, and claim 10 is anticipated.

Conclusion

Claims 3 and 5-13 are rejected and claims 8-9 are objected to. Claims 3 and 11-13 appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a Patent Analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Marjorie A. Moran
July 16, 2001

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